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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/989,684	11/20/2001	David Samuel Cohen	BTI2 00102601 (USP)US	9719
20995	7590	04/20/2006		
KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			EXAMINER SIEFKE, SAMUEL P	
			ART UNIT	PAPER NUMBER
			1743	

DATE MAILED: 04/20/2006

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/989,684
Filing Date: November 20, 2001
Appellant(s): COHEN ET AL.

MAILED

APR 20 2006

GROUP 1700

Russell M. Jeide
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 11/10/05 appealing from the Office action
mailed 5/04/05.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

6,030,581

Virtanen

2-2000

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims **9, 12, 25-31, 77-78** are rejected under 35 U.S.C. 102(e) as being anticipated by Virtanen (USPN 6,030,581).

Virtanen discloses a laboratory in a disk that comprises: an optical disk, adapted to be read by an optical reader, comprising a first sector having a self-contained assay means for localizing an analyte suspected of being in a sample. The disk comprises a sample entry chamber (14), and a separation zone (17) downstream of the entry

chamber (fig. 2A). The separation zone specifically separates the analyte from the sample. Filters are included as part of the sample inlet, and are formed from porous plastic, glass, cellulose, etc. These materials may be in the shape of rods or similar shapes depending on the particular use to which they are being applied (col. 7, lines 35-43). Further the filters may be used to removed large particles, such as cells, dust, etc. from the soluble sample. The filters may be formed from porous plastic, glass, cross-linked cotton or cellulose, etc (col. 7, lines 36-43). The filters above anticipate the separation structure of the instant application. It is noted that these may be in the sample inlet, but are located downstream from the entry chamber (col. 7, lines 54-65). The optical disk includes a substrate including tracking grooves (col. 5, lines 21-23) and a reflective layer formed on the substrate (col. 7, lines 9-35) so that an incident beam can track along the groove (col. 4, lines 17-61) where a reader detects information that identifies the particular analyte (col. 5, lines 35-53). Virtanen further discloses tracking grooves as capillary ducts and fluid storage and retention compartments that are machined into the optical disk or formed by chemical means or injection molding operations. The depths are about 1-2000 um preferably about 10-800 um and they may have any shape possible (col. 6, lines 55-60). With respect to quantifying the agglutinants in the entry chamber by determining an amount of the tracking groove that is at least partly covered by particle agglutinants, Virtanen discloses the analytes bind to a predetermined location on the disk if it is present in the sample and the presence of the analyte is detected by the reader from information that identifies the particular analyte with the location at which it is bound (col.5, lines 44-47). A multiplicity of assay

sectors 21,22,23 as shown in figure 3 may be provided, each sector connected to an individual sample inlet port 24, 25, 26 respectively. The liquid flow during the assay may be monitored by using a reflective element. The reflective element utilizes the laser that is in the CD or DVD reader and the fact that even when the liquid is transparent its reflective index is significantly different from that of air. The optical disk further comprises a collection zone (20) downstream of the separation zone (fig. 2A). The optical disc includes a mixing chamber (15) where buffers can be mixed with the sample (col. 5, lines 25-35). The optical disc contains a center where the sample is added and upon rotation the sample migrates toward the outside of the disc in the order of sample entry, separation zone, collection zone (fig. 2A, 3).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims **15-24** and are rejected under 35 U.S.C. 103(a) as being unpatentable over Virtanen (USPN 6,030,581).

Virtanen discloses a laboratory in a disk that comprises: an optical disk, adapted to be read by an optical reader, comprising a first⁺ sector having a self-contained assay means for localizing an analyte suspected of being in a sample.

Virtanen does not teach specifically that the separation zone includes series of slits formed in the substrate to allow small particles to pass through, along with how these structures are described (rib, increasing and decreasing size of the slits). It would have been obvious to modify Virtanen to include such a separation zone as described above because it is known in the art of particle separation that creating slits or ribs that decrease in size allows for larger particles to be separated from the sample and allowing^S smaller particles to continue on through the separation zone. With respect to the optical disc of Virtanen teaching a material holding zone that holds freeze-dried bioactive agent material, Virtanen teaches a sample prep area (fig. 1A) that includes agents that prepare the sample for separation (col. 12, lines 45-67). It would have been obvious to one having an ordinary skill in the art to modify Virtanen to include freeze-dried bioactive agent material in the sample preparation zone ~~unstable~~ in order to provide a disc which is ready-for-use[!] and has a stable, extended shelf life.

(10) Response to Argument

Discussion of Disperse Particle Quantification

Appellant argues, "Virtanen does not teach or suggest that "a quantity of disperse particles may be determined," as recited by claim 77. Virtanen does not teach or suggest quantitating disperse particles using a detector "to count a number of the plurality of tracks that are covered by the disperse particles." Tracking grooves can be in the broadest interpretation, grooves in a substrate that allow a liquid to move where they can be tracked. Virtanen does just this by disclosing a path (groove) by which an analyte can move through and bind to a predetermined location on the disk and if it is present in the sample, the presence of the analyte is detected by the reader from information that identifies the particular analyte with the location at which it is bound (col.5, lines 44-47). Further Virtanen discloses the integrated biocompact disc is a universal analyzer that can perform DNA testing, cell counting and cell shape measurement (col. 14, lines 34-50). Cell counting is a way of quantitating how many cells are in a sample. An optical detector counts the number of cells in the sample. Therefore, Virtanen discloses the above limitations in claims 9, 77 and 78.

There are no arguments regarding claims 15-24 other than they depend from claim 9 and are believed to be allowable based on the arguments presented regarding claim 9.

(11) Related Proceeding(s) Appendix

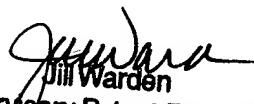
No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Sam P. Siefke




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Supervisory Patent Examiner
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Conferees:

Jill Warden

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APPEAL CONFeree: 